




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 22 2013

OFFICE OF WATER

MEMORANDUM

SUBJECT: Response to "Approval to use 'two concentrations only' experimental design with EPA's Test of Significant Toxicity (TST) hypothesis testing approach"

FROM:  Robert Wood, Director, Engineering and Analysis Division
Office of Science and Technology (OST)

TO: Alexis Strauss, Deputy Regional Administrator
U.S. EPA Region 9

Thank you for your letter to Betsy Southerland requesting OST's "*Approval to use 'two concentrations only' experimental design with EPA's Test of Significant Toxicity (TST) hypothesis testing approach.*" Betsy asked me to respond on her behalf. We understand you are requesting approval for NPDES permits issued in Region 9 to require only two concentrations (a control plus one effluent concentration) only when evaluating whole effluent toxicity (WET) results using the EPA's 2010 Test of Significant Toxicity (TST) statistical approach. We have reviewed your memo and the TST documentation and, as we have indicated to your staff, we are not challenging the technical or programmatic merits of the TST statistical approach to analyze valid WET test data or the appropriateness of only two concentrations in this specific application. Rather, as stated in the promulgated CWA WET methods and re-iterated in the "EPA's National Pollutant Discharge Elimination System Test of Significant Toxicity Implementation Document," these methods require a control plus five effluent concentrations under the methods' test acceptability criteria. As such, the promulgated methods do not allow for only two concentrations for use in NPDES permits. Recognizing that modifications to promulgated methods that are outside the scope of the method's flexibility may be appropriate, 40 CFR Part 136 defines a process that allows for such modifications. Therefore, the appropriate venue to consider the modification you are requesting is the Alternate Test Procedure (ATP) program, as described in 40 CFR 136.4 and 40 CFR 136.5 which allows for both limited use ATPs and nationwide ATPs.

As we have indicated to your staff, we do not yet have guidance for requesting or evaluating WET ATP requests as described in 40 CFR Part 136.4 and 136.5. We are developing that guidance for both limited use and nationwide WET ATPs and plan to issue it in December, 2013. That guidance will include information on the data, analysis, and documentation that should be submitted and evaluated for any WET ATPs evaluations. As such, it would be appropriate to consider an ATP to address your request after we have established clear guidance. Moreover, as specified in 40 CFR Part 136.4 and 136.5, limited use ATP requests are evaluated and approval is determined by the Regional Administrator (or their designee) and nationwide ATP requests are evaluated by the ATP Program Coordinator in my office. Because the exception you are describing would apply only for specific applications in NPDES permits in your Region rather than nationwide, as specified in 40

CFR Part 136.4 and 136.5, it is appropriate for consideration as a limited use ATP. Such ATP requests are evaluated and approval is determined by the Regional Administrator (or their designee) rather than the ATP Program Coordinator in my office. Therefore, even in absence of specific guidance for WET ATPs, Region 9 already has the authority to accept, review, and approve a limited use ATP for the specific application described in your memo. We suggest the State of California apply for a WET ATP for this specific application and that Region 9 review and, as appropriate, approve that application.

If you or your staff has additional questions about the ATP program, please call me at (202) 566-1822.

cc: David Smith, Region 9
Eugenia McNaughton, Region 9
Ross Brennan, OWM
Tom Lavery, OWM
Deborah Nagle, OWM
Jan Matuszko, OST
Janet Goodwin, OST
Elizabeth Southerland, OST